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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,619	11/10/2005	Stephen Jane	DAVI251.001APC	1433

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EXAMINER

SGAGIAS, MAGDALENE K

ART UNIT PAPER NUMBER

1632

DATE MAILED: 06/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/524,619

Applicant(s)

JANE ET AL.

Examiner

Magdalene K. Sgagias

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-21 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                                    | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

1. Claims 1-21 are pending.

***Election/Restrictions***

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-6, drawn to an isolated nucleic acid molecule comprising a sequence of nucleotides encoding or complementary to a sequence encoding a mammalian transcription factor comprising an amino acid sequence having at least 75% identity to SEQ ID NO: 8 or SEQ ID NO: 16.

Group II, claim(s) 7-10, 16, drawn to a pharmaceutical composition for the treatment of a genetic or physiological disorder comprising: an isolated nucleic acid molecule comprising a sequence of nucleotides encoding or complementary to a sequence encoding a mammalian homolog of *Drosophila* grh wherein the nucleic acid molecule encodes a transcription factor selected from a panel of nucleic acid sequences.

Group III, claim(s) 11, drawn to a method of identifying a nucleotide sequence likely to encode a M-GRH transcription factor, said method comprising: interrogating a mammalian genome database conceptually translated into different reading frames with an amino acid sequence defining *Drosophila* GRH or any one of the sequences selected.

Group IV, claim(s) 12, drawn to a method for treating spinabifida or other physiological or genetic disorders in a patient comprising administering to said patient an isolated mammalian transcription factor which is a selected homolog of *Drosophila* grainyhead (GRH).

Group V, claim(s) 13, drawn to a method for detecting an embryo with a propensity to develop spinabifida said method comprising contacting said embryo or a cell thereof with agents capable of detecting the level of expression of a selected transcription factor.

Group VI, claim(s) 14-15, drawn to an animal model comprising a genetically modified animal comprising a nucleotide insertion, deletion, and/or substitution in a nucleic acid molecule comprising a nucleotide sequence having at least 75% identity after optimal alignment to one or more of the selected polynucleotide.

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Group VII, claim(s) 17-19, drawn to an isolated polypeptide comprising an amino acid sequence having at least 60% identity to SEQ ID NO: 8 or SEQ ID NO: 16 after optimal alignment.

Group VIII, claim(s) 20, drawn to a pharmaceutical composition for the treatment of a patient with a genetic or physiological disorder, comprising the isolated polypeptide, wherein the isolated polypeptide comprising an amino acid sequence having at least 60% identity to SEQ ID NO: 8 or SEQ ID NO: 16 after optimal alignment.

Group IX, claim(s) 21, drawn to a method of treating spinabifida or other physiological or genetic disorders in a patient, comprising: administering to said patient the isolated polypeptide, wherein the isolated polypeptide comprising an amino acid sequence having at least 60% identity to SEQ ID NO: 8 or SEQ ID NO: 16 after optimal alignment.

The inventions listed as Groups I-IX do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The invention of Group I does not require the panel of selected nucleic acid molecules which encode for a transcription factor of Group II. An international and a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single inventive concept. Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. See 37 C.F.R. 1.475 (a). If multiple products, processes of manufacture, or uses are claimed, the first invention of the category first mentioned in the claims of the application and first recited invention of each of the other categories related thereto will be considered as the main invention in the claims. See 37 C.F.R. 1.475 (d) and 37 C.F.R. 1.476 (c). Accordingly, Groups I-II are not linked by a special technical feature.

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3. Because these inventions are distinct for the reasons given above, have acquired a separate status in the art shown by their recognized divergent subject matter and because each invention requires a separate, non-coextensive search, restriction for examination purposes as indicated is proper.


Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 C.F.R 1.48(b) and the fee required under 37 C.F.R 1.17(i).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Magdalene K. Sgagias whose telephone number is (571) 272-3305. The examiner can normally be reached on Monday through Friday from 9:00 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram R. Shukla, can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Magdalene K. Sgagias, Ph.D.  
Patent Examiner  
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